



Billing Code 4165-15

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Health Resources and Services Administration**

#### **Agency Information Collection Activities: Proposed Collection: Public Comment Request; Organ Procurement and Transplantation Network**

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Notice

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this Information Collection Request must be received no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or by mail to the HRSA Information Collection Clearance Officer, at 5600 Fishers Lane, Room 14N39, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain copies of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Organ Procurement and Transplantation Network  
OMB No. 0915-0184 – Revision

Abstract: HRSA is proposing additions and revisions to the following documents used to collect information from existing or potential members of the Organ Procurement and Transplantation Network (OPTN). The documents under revision include: (1) application forms for individuals or organizations interested in membership in OPTN, (2) application forms for OPTN members applying to have organ-specific transplant programs designated within their institutions, and (3) forms submitted by OPTN members to report certain personnel changes.

Need and Proposed Use of the Information: Membership in the OPTN is determined by submission of application materials to the OPTN (not to HRSA) demonstrating that the applicant meets all required criteria for membership and will agree to comply with all applicable provisions of the National Organ Transplant Act, as amended, 42 U.S.C. 273, et seq (NOTA), OPTN Final Rule, 42 CFR Part 121, OPTN bylaws, and OPTN policies. Section 1138 of the Social Security Act, as amended, 42 U.S.C. 1320b-8 (section 1138) requires that hospitals in which transplants are performed be members of, and abide by, the rules and requirements (as approved by the Secretary of HHS) of the OPTN, including those relating to data collection, as a condition of participation in Medicare and Medicaid for the hospital. Section 1138 contains a similar provision for organ procurement organizations (OPOs) and makes membership in the OPTN and compliance with its operating rules and requirements, including those relating to data collection, mandatory for all OPOs. The membership application forms listed below enable prospective OPTN members to submit the information necessary for OPTN to make membership decisions. Likewise, the designated transplant program application forms listed below enable OPTN members to submit the information necessary for OPTN to make designation decisions.

New membership forms have been created for transplant centers seeking to perform Vascularized Composite Allograft (VCA) transplants, a new and emerging field. VCAs were added to the set of organs covered by NOTA and the OPTN final rule via regulation, effective July 3, 2014. The OPTN Board approved OPTN membership requirements for VCA programs in late 2015. Because a transplant center applying to be an OPTN-approved VCA transplant program must already have current OPTN approval as a designated transplant program for at

least one other organ, the VCA membership forms were developed based on existing membership forms.

To keep pace with scientific and clinical advances in the field of transplantation, HRSA plans to submit a clearance package to OMB after reviewing comments to this notice. New forms and revisions to the current OPTN forms include the following:

- Organ-specific program and histocompatibility laboratory applications reflecting key personnel requirement revisions made to the OPTN bylaws (the bylaws revisions will be implemented upon approval of these forms).
- Program applications based on existing organ-specific application forms, for programs seeking intestinal and VCA transplantation approval OPTN-defined VCAs: VCA head and neck, VCA upper limb, VCA abdominal wall kidney, VCA abdominal wall liver, VCA abdominal wall pancreas, VCA abdominal wall intestine, and VCA other.
- Intestine program applications, based on an existing organ-specific application form.
- Cover pages, based on existing cover pages for other organ types, have been created for VCA new transplant program, VCA key personnel change, VCA other new transplant program, and VCA other key personnel change.
- Questions and tables reflecting new ordering and numbering for improved flow on various forms.

The burden of completing the new and revised forms is expected to be minimal, as these forms are based on OPTN membership applications that organizations have completed in the past.

Likely Respondents: Likely respondents to this notice include the following: hospitals performing or seeking to perform organ transplants, organ procurement organizations, and medical laboratories seeking to become OPTN-approved histocompatibility laboratories.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested, including the time needed to (1) review instructions; (2) develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and transmitting, disclosing, or providing information; (3) train personnel to respond to a collection of information; (4) search data sources; (5) complete and review the information collected; (6) and transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
A. New Transplant Member Application-General	2	1	2	8	16
B Kidney (KI) Designated Program Application	118	2	236	4	944
B Liver (LI) Designated Program Application	59	2	118	4	472

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
B Pancreas (PA) Designated Program Application	60	2	120	4	480
B Heart (HR) Designated Program Application	92	2	184	4	736
B Lung (LU) Designated Program Application	30	2	60	4	240
B Islet (PI) Designated Program Application	2	2	4	3	12
B Living Donor (LD) Recovery Program Application	42	2	84	3	252
B VCA Head and Neck Designated Program Application	14	2	28	3	84
B VCA Upper Limb Designated Program Application	17	2	34	3	102
B VCA Abdominal Wall* Designated Program Application	13	2	26	3	78
VCA Abdominal Wall – Kidney					
VCA Abdominal Wall – Liver					
VCA Abdominal Wall – Pancreas					
VCA Abdominal Wall – Intestine					
B VCA Other** Designated Program Application	9	2	18	2	36
B Intestine Designated Program Application	40	2	80	3	240
C OPO New Application	0	1	0	4	0
D Histocompatibility Lab Application	3	2	6	4	24
E Change in Transplant Program Key Personnel	395	2	790	4	3160

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
F Change in Histocompatibility Lab Director	25	2	50	2	100
G Change in OPO Key Personnel	10	1	10	1	10
H Medical Scientific Org Application	7	1	7	2	14
I Public Org Application	4	1	4	2	8
J Business Member Application	2	1	2	2	4
K Individual Member Application	4	1	4	1	4
Total = 25 forms	948		1867		7016

\*VCA Abdominal Wall Designated Program qualification requirements require documentation on VCA Head and Neck, VCA Upper Limb, Kidney, Liver, Intestine, or Pancreas program requirements.

\*\*VCA Other Designated Program Application data based on four categories of “others” including genitourinary and lower limb as defined by the OPTN bylaws.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency’s functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

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